

3/September/97

A copy of these two insurance policies is included in this contract as ATTACHMENT 5.

**12<sup>th</sup> - TRANSFER PROHIBITION.-**

BELMAC can not cede, transmit or transfer to another person or persons, either in individuals or judiciary, the present contractor any of the rights within it, without prior written consent from ETHYPHARM.

**13<sup>th</sup> - NO COMPETITION.-**

BELMAC is forbidden, during the duration of the present contract and beyond, until such information and the know-how becomes public domain through sources other than ETHYPHARM to manufacture the products with the technology that ETHYPHARM has made available to BELMAC, without their precise authorization. However, ETHYPHARM will guarantee the provision of products in pellets for BELMAC and their possible clients after this contract has expired.

**14<sup>th</sup> - SOCIAL AND LABOR RELATED OBLIGATIONS.-**

ETHYPHARM will not be responsible for any labor duties from BELMAC or the lack of compliance with any safety rules for their workers.

No link can be established at any time between ETHYPHARM and the workers hired by BELMAC engaged in the manufacturing of the products.

**15<sup>th</sup> - DISSOLUTION OF THE CONTRACT.-**

The lack of compliance from any of the conditions of this contract and its ATTACHMENTS will be cause for the dissolution of the contract:

a- BELMAC's failure to make payments or it's filing for bankruptcy.

b- An essential change (of equal or higher than 25%) directly or indirectly, within the BELMAC stockholders contributing to the public holdings. ETHYPHARM would be authorized to dissolve the contract, in the event of any change among the stockholders, where an individual or a company, who does not belong to the present stockholders of BELMAC, becomes part of it. BELMAC pledges to communicate by certified mail any significant change (equal or higher than 25%) from its capital, different than disclosed previously.

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**16<sup>th</sup> - CHANGES.-**

The responsibilities acquired in this contract cancel all of the previously existing between all parties, as well as those contracts regulating them, still in effect, which are totally void in every aspect and specially those pertaining to the changes determined by article 1204 of the civil law. Despite that, all agreements referring to the pacts of secrecy and confidentiality remain in effect for all parties, until they become an integral part of this contract and applicable to the same.

**17<sup>th</sup> - VISITATION.-**

ETHYPHARM or any person designated through them, is authorized to carry out inspection and/or audit visits inquiries or any of a general nature to the BELMAC facilities to confirm the regular manufacturing procedures of the products and the proper utilization of the equipment as well as compliance with the rules of Quality Assurance; including those of personnel development, with advance notice.

**18<sup>th</sup> - DOCUMENTATION.-**

BELMAC is committed to the preparation, filing and safekeeping of the documentation established by the Royal Decree (*Real Decreto* 1.564/1.992) of December 18<sup>th</sup> (specifically article 35). In addition it promises to provide ETHYPHARM the documents of the manufactured lots.

**19<sup>th</sup> - MANUFACTURING STEPS.-**

The steps of production or product analysis and the corresponding technical rules, signed by the Technical Directors of each part are included in ATTACHMENT 6, in compliance with the requirements stipulated in article 29 of the Royal Decree (*Real Decreto*) 1.564/1.992, of December 18<sup>th</sup>.

**20<sup>th</sup> - ARBITRATION.-**

Regarding any questions that may arise, concerning the performance or to the resolution of the present document, all parties -- waiving their right to common judiciary proceedings- will turn to arbitration by a mediator appointed by the **CHAMBER OF COMMERCE AND INDUSTRY OF MADRID**. All parties abide to follow the resolutions from verbal testimonies as well as the final decision. The maximum time for this decision is six months, from the mediator's acceptance to the resolution of the controversy, which has to be carried out within fifteen days after the notice is stated.

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Both parties, being fully informed of the judiciary and financial contents of this document, have acknowledged the legitimacy of the document and they have signed it jointly including all the ATTACHMENTS by duplicate on the date and location stated at the beginning.

Signed. ETHYPHARM S.A., on behalf of.

Signed. LABORATORIOS BELMAC, S.A., on behalf of.

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**ATTACHMENT 1**

**PRODUCTS**

- Indomethacin
- Diclofenac
- Piroxicam
- Omeprazol
- Lansoprazole
- AAS\*
- Penofibrate\*
- Doxycycline

\* Could not find English Name

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**ATTACHMENT 2**

- Documents, GMP norms, validations
- Photocopie BELMAC page
- Index of the manufacturing and control files

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### ATTACHMENT 3

The equipment from ETHYPHARM, which is their property, are the following:

- 1 SIEMENS OP 393-II AUTOMAT
- ~~CUADRO PROGRAMADOS DE SALAS\*~~
- ~~4 AUTOMATAS DE SALAS DEPENDIENTES DEL GENERAL\*~~
- ~~8 PULAS\*~~ REF.150 RE + 8 HOT AIR INSUFLATOR REF.3R
- 4 PULVERIZING OUTFITS (9 GUNS AA3000 + 8 STANDS FOR GUNS + 4 PRESSURE PUMPS + 4 PEDALS + TIPS)
- 3 WESTON VIBRATING MAT REF. 503-3 + 29 RINGS WITH MESH/ 7 SUPPORT RINGS/SUPPORT MESH
- 23 CONTAINERS WITH HANDLES AND LIDS
- 1 MICRONIZER PORPLEX 00 + 0.1 mm MESH
- 1 ELECTRONIC MINITHERMOMETER TYPE ABMI 1.03 + PROBE REF. A2864441
- 8 SUPPORTS FOR FLOW CONTROL BLADES
- 1 DISOLUTEST
- 1 TERMINAL ~~DE PESADA\*~~ METTLER MULTIRANGE IDS
- 1 MULTIRANGE METTLER PRINTER GD46
- 1 FIXED DOWN FLOOR BALANCE KCS 300
- 1 METTLER PJ12 SCALE
- 2 20 Kgs WEIGHTS TO CALIBRATE SCALE
- 1 MACHINE FOR CAPSULES COMPAC MODEL FORMAT 1,2 AND ACCESSORIES
- 1 CAPSULE SELECTOR MG2
- 1 FILING CABINE
- 1 CALIBRATING CHART T1
- 1 EPSON ORGANIZER Px 16
- 1 METTLER PRECISION SCALE PM100
- 1 ONE PUMP FOR ~~DESARROLLOS GALENICOS\*~~
- 1 INOX JM D-250 STIRRER

#### Small Equipment

- 1 LADDER
- 3 CALCULATORS AND OFFICE MATERIAL (FILING CABINETS, MATS)
- 2 BRUSHES special type
- 3 DESKS
- 4 SHORT HANDLE BLADES INOX
- 2 INOX CUBES 101
- 2 INOX FLASKS
- 4 INOX SPATULAS
- WALL CLOCK
- 1 SPECIAL CLEANING EQUIPMENT IN ~~PLA\*~~
- 1 KNIFE

\* in italics = Could not find proper technical translation

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\*\*\*\*

This page did not print out well and I can barely read the letters and the numbers.

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EP009188

- PVA sponge, clamp for the sponge, Expandable handle

LIST OF DISMANTABLE EQUIPMENT

Plumbing:

- Sink
- Eyewash station
- Fountain

Compressed Air/Extraction:

- Air extraction turbine
- Filter bags

Climate Control:

- Independent refrigeration system

Lighting:

- Lamps with soft light

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**ATTACHMENT 4**

Annual Surplus: 30 M pts.

BONUS TO BELMAC

Beginning after 17 lots 600 000. - Pts per each lot

Beginning after 27 lots 700 000. - Pts per each lot

Beginning after 37 lots 800 000. - Pts per each lot

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ATTACHMENT 5

INSURANCE:

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EP009191



Fax émis par : 33141121797

ETHYPHARM ST CLOUD

A4-&gt;A4 03/04/98 17:00 Pg: 2/10

D. Clemente GONZALES AZPETA, in the name and in representation of LABORATORIOS BELMAC S.A., with registered office in Monteraagon, N°9 28033 MADRID (Spain) and with tax identification Number A- 78964038, as General Manager

Mr James R. MURPHY in the name and representation of BENTLEY PHARMACEUTICALS INC. - with registered office in One Urban Centre, Suite 548, 4830 Was Kennedy Boulevard, TAMPA - FLORIDA 33609-2562 - USA as Chairman and Chief Executive Officer

**HEREBY CERTIFIES THAT**

ETHYPHARM S.A. (Spain) (« ETHYPHARM ») has a manufacturing agreement with LABORATORIOS BELMAC S.A. for manufacturing omeprazole pellets in LABORATORIOS BELMAC S.A.'s plant in Zaragoza.

LABORATORIOS BELMAC S.A. is audited regularly by ETHYPHARM to assure that GMP are followed under ETHYPHARM's Q.A. requirements.

ETHYPHARM owns, among other elements, the manufacturing and control methods, processes, the technology and know-how (« the Information ») for a certain number of products in pellets among which Omeprazole pellets and its derivatives (« the Products ») and is the owner of the machinery and certain control equipment employed by LABORATORIOS BELMAC S.A. for the manufacturing of said Products.

Said Information has been transmitted to LABORATORIOS BELMAC S.A. by ETHYPHARM only for the purpose of manufacturing the Products for ETHYPHARM's customers including LABORATORIOS BELMAC S.A. within the framework of agreements between the parties.

As a consequence, LABORATORIOS BELMAC S.A., and any of its related companies, among which BENTLEY PHARMACEUTICALS Inc., undertakes not to divulge the Information to third parties and not to use any of the Information and machinery for any other purpose than the manufacturing of the Products for ETHYPHARM's customers.

LABORATORIOS BELMAC S.A. recognizes that all the information and machinery is the sole property of Ethypharm and that LABORATORIOS BELMAC S.A. shall stop using it and return it immediately to ETHYPHARM upon termination of the collaboration between LABORATORIOS BELMAC S.A. and ETHYPHARM.

In the event of a breach of the present undertaking ETHYPHARM reserves the right to claim for damages.

03/04 '98 17:03  
CONFIDENTIAL

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P.002

BEL000256

A-276

Fax émis par : 33141121797

ETHYPHARM ST CLOUD

04-04 03/04/98 17:00

Pg: 3/10

## Supply Contract

BETWEEN THE UNDERSIGNED :

■ **ETHYPHARM S.A. Spain, Centro Colon (1220), 28004 MADRID, SPAIN**

Represented by its President : Mr. Patrice DEBREGEAS

Hereinafter called **ETHYPHARM**

**OF THE FIRST PART**

AND :

■ Represented by its:

Hereinafter called **THE LABORATORY**

**OF THE SECOND PART**

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**CONFIDENTIAL**

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**A-277**

Fax émis par : 33141121797

ETHYPHARM ST CLOUD

04-04

03/04/98

17:00

Pg: 1/10

ETHYPHARM  
Marques de la Ensamada 16  
28004 Madrid

Tel : 34 91 308 56 81

Fax : 34 91 3 19 91 59

Date : 03/04/1998

Nb pages :

From : Adolfo de Basilio

To : C. Gonzalez

Fax : 38876 47

Company : Belmac

MESSAGE

Señor

A continuación pasamos la carta que Ethypharm propone para su firma por Belmac y Bentley y el borrador de contrato para Omeprazol.

Saludos

Adolfo de Basilio

03/04 '98 17:03

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P.001

CONFIDENTIAL

BEL000259

A-278

Fax émis par : 33141121797 ETHYPHARM ST CLOUD A4-A4 03/04/98 17:08 Pg: 3/10

## Supply Contract

BETWEEN THE UNDERSIGNED :

■ ETHYPHARM S.A. Spain, Centro Colon (1220), 28004 MADRID, SPAIN

Represented by its President : Mr. Patrice DEBREGEAS

Hereinafter called ETHYPHARM

OF THE FIRST PART

AND :

■ Represented by its:

Hereinafter called THE LABORATORY

OF THE SECOND PART

03/04 '98 17:03  
CONFIDENTIAL

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P.003

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A-279

Fax émis par : 33141121797

ETHYPHARM ST CLOUD

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03/04/98

17:00

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ETHYPHARM has developed the pharmaceutical formulation of the Product defined in Annex A and hereinafter called "the Product".

THE LABORATORY has been granted a marketing authorisation for the Product, hereinafter referred to as "the Marketing Authorisation" in .....

THE LABORATORY is interested in receiving all its needs in the Product from ETHYPHARM for its distribution in the Territory. ETHYPHARM agrees to supply THE LABORATORY with the Product for ....., hereinafter referred to as "the Territory", under the conditions set forth in the present Contract provided THE LABORATORY undertakes to order all its supplies in Product for the Territory exclusively from ETHYPHARM and comply with the terms of the present Contract.

Therefore, it has been agreed as follows :

#### Article I - Supply.

During the period of this Contract ETHYPHARM will supply for the Territory, such quantities of the Product as will be required by THE LABORATORY.

#### Article II - Exclusivity.

The counterpart of the engagement of guaranteed supplies by ETHYPHARM to THE LABORATORY under article I above is that THE LABORATORY will take all its supplies exclusively from ETHYPHARM or from another supplier designated by ETHYPHARM for all its needs of the Product in the Territory in order to guarantee the quality of the Product. Moreover, THE LABORATORY may not directly or indirectly manufacture microgranules constituting the Product. ?

#### Article III - Orders.

III.1. THE LABORATORY will place its orders at least four (4) months in advance according to its predicted annual requirement, revised every six (6) months.

The said predicted annual requirement will be communicated by THE LABORATORY for information purposes, sixty (60) days before the start of each calendar year and will not constitute a firm commitment by THE LABORATORY.

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A-280



Each order placed by **THE LABORATORY** will bear the exact quantity ordered, the delivery date and the address at which the Product must be sent.

The orders will be considered as firm and irrevocable and will bind **ETHYPHARM** as soon as accepted in writing.

**ETHYPHARM** shall accept and deliver all the orders according to the program established by **THE LABORATORY** unless the quantities ordered are substantially different from the quantities indicated in **THE LABORATORY**'s forecasts for the year of the Contract and provided that **ETHYPHARM** receives the order a minimum of four (4) months before the delivery date.

**THE LABORATORY** shall at all times keep adequate stock of the Product to meet the market demand in the Territory. These adequate stocks shall be sufficient for covering the estimated requirement for at least four (4) months.

III.2. In the event of being unable to fulfil its obligations as supplier, for whatever reason, **ETHYPHARM** undertakes to inform **THE LABORATORY** with the minimum delay possible and to find another supplier within a maximum of sixty (60) days. The latter will deliver the order within thirty (30) days on the same terms and conditions.

III.3. Technical and pharmaceutical responsibility and obligations of the parties will be fully detailed in an "Agreement on Contract Manufacturing of Drug" to be established between the technicians of the parties.

#### Article IV - Prices.

The supply price of the Product invoiced by **ETHYPHARM** to **THE LABORATORY** will be determined by mutual agreement between the parties according to the conditions set out in Annex B hereto.

#### Article V - Liability.

**ETHYPHARM** shall accept responsibility for any claims covered by and limited to the guarantees specified in the insurance policy annexed hereto arising out of latent or hidden defects in the Product which could not have been reasonably discovered by **THE LABORATORY**'s inspection but will not be held responsible for any side effect currently unknown inherent to the characteristics of the Product which is manufactured strictly in accordance with the provisions defined by the registration files accepted by the local Regulatory Authorities.

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**Article VI - Indemnity.**

**THE LABORATORY** shall be exclusively liable for any damages, claims or losses from which **THE LABORATORY** may suffer by reason of improper packaging, storage, re-packaging, distribution, promotion, marketing and advertising of the Product in the Territory. **ETHYPHARM** will, however, be responsible as to the good manufacturing practice and good storage facilities in its plant and warehouses until the goods are collected by **THE LABORATORY**.

**Article VII - Product recall and adverse reactions.**

Each party shall use reasonable endeavours to obtain and record written medical confirmation and relevant details of all suspected or alleged reactions to the Product (hereinafter called "Adverse Reactions") and shall ensure by means of a written log that all such cases and the dossier relative to it is uniquely identified and retrievable.

**Article VIII - Quality.**

**VIII.1. ETHYPHARM** shall be responsible for ensuring that, when released by **ETHYPHARM**, the Product accord to the specifications set out in Annex A hereto. If the Product is found not to comply with the specifications by local testing authorities, within one (1) month from receipt by **THE LABORATORY** of the Product, **THE LABORATORY** shall have the right to demand a refund or replacement thereof and to return the defective quantity to **ETHYPHARM** at **ETHYPHARM**'s expense. In case of disagreement between the parties as to the compliance of the Product with the specifications, the parties agree to have the Product controlled by an independent expert chosen by the parties and acceptable to the local testing authorities. The results of such retesting will be binding and the party found in default will bear the costs of retesting and replacement of the Product.

**VIII.2. THE LABORATORY** and the competent Authorities of the Territory will have the right to inspect **ETHYPHARM**'s production of the Product, at any time, following reasonable notice and during office hours.

**Article IX - Insurance.**

**ETHYPHARM** and **THE LABORATORY** warrant that they hold adequate products liability insurance in respect of any claims which may be brought against **ETHYPHARM** or **THE**

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BEL000263

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**LABORATORY** in relation to the Product and will supply each other with a copy of the relevant policy on request.

#### **Article X - Duration.**

This Contract shall be effective immediately upon its signature and shall remain into effect for a period of ten (10) years from the date of first launch of the Product in the Territory. *new techol-*

At the end of this initial period of ten (10) years, this Contract will be automatically renewed per periods of three (3) years unless terminated by any of the parties twelve (12) months prior to the end of the initial period or any of the renewal period by registered mail.

#### **Article XI - Termination.**

Each party reserves the right to cancel this Contract at any time and without indemnification if the other party commits a material breach of its obligations and fails to remedy this breach within ninety (90) days of the notification of said breach by registered letter.

#### **Article XII - Confidentiality.**

All the information relative to the Product or to the know-how communicated by **ETHYPHARM** to **THE LABORATORY**, will be considered by **THE LABORATORY** as strictly confidential and will not be divulged by **THE LABORATORY** to third parties without prior agreement in writing by **ETHYPHARM**. The subsidiaries, licensees, or overseas agents of **THE LABORATORY** outside the Territory are considered as third parties.

This obligation shall continue for five (5) years beyond the expiry of this Contract for any reason. Nevertheless, it will not apply to information which must be given to physicians for sales purposes or to the authorities for the purpose of registering the Product in the Territory.

#### **Article XIII- Contractual relationship.**

**XIII.** This Supply Contract constitutes the whole agreement between the parties and replaces any former agreement relative to the same subject. Modifications to this Contract will be made in writing only, and will have to be accepted and signed by both parties.

**XIII.** If one of the provisions of the present Supply Contract interferes with local legislation in force in the Territory, then this particular provision will be modified by the parties in order to comply with local legislation. This modification will not affect the other provisions of this Contract.

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ETHYPHARM ST CLOUD

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#### **Article XIV - Jurisdiction.**

In the event of difficulties between the parties as to the interpretation of this Agreement, the parties agree to submit these difficulties to the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the Rules and decisions of the ICC. The arbitrator (s)' decisions shall be binding on both parties hereto.

The applicable law will be Spanish law and arbitration place will be Madrid (Spain). The arbitration proceedings will be conducted in English language.

#### **Article XV - Transfer.**

THE LABORATORY may not transfer its rights or obligations arising from this Contract without the prior written consent of ETHYPHARM.

#### **Article XVI - Costs and fees.**

The costs and fees of any possible registration or legalisation of this Contract are to be borne by THE LABORATORY.

Signed in  
For :

Date :  
For : ETHYPHARM S.A. Spain  
Patrice DEBREGEAS  
President

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CONFIDENTIAL

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Fax émis par : 33141121797 ETHYPHARM ST CLOUD A4->A4 03/04/98 17:00 Pg: 18/18

**Annex B to the Supply Contract between**

**..... and ETHYPHARM S.A. Spain**

The supply exclusivity defined in Article II means that THE LABORATORY will take exclusively from ETHYPHARM all its requirements of the Product.

1.1. The supply price of the Product, delivered in ....., is expressed ..... and fixed at :

- 20 mg : ..... per thousand doses taxes excluded.

This price includes .....

Moreover, it is valid for minimum batches of doses corresponding to .....

1.2. Should THE LABORATORY wish to order a smaller quantity than the standard batch above mentioned ETHYPHARM may apply a supplement of 30 % of the price if the quantity lies between 50 % and 100 % of a normal batch and a supplement of 50 % of the price if the quantity ordered is less than 50 % of the normal batch.

2. All payments will be made by ..... within ..... from date of shipment of goods from ETHYPHARM (date of AWB for example).

3. The price set out in this Annex is guaranteed until ..... and will vary each year in accordance with the salary increase of the "Convenio de la Industria Quimica" in Spain.

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CONFIDENTIAL

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Fax émis par : 33141121797

ETHYPHARM ST CLOUD

A4-A4 03/04/98 17:00

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*par rapport*

ETHYPHARM has developed the pharmaceutical formulation of the Product defined in Annex A and hereinafter called "the Product". *micropharm de souppes*

THE LABORATORY has been granted a marketing authorisation for the Product, hereinafter referred to as "the Marketing Authorisation" in.....

THE LABORATORY is interested in receiving all its needs in the Product from ETHYPHARM for its distribution in the Territory. ETHYPHARM agrees to supply THE LABORATORY with the Product for ....., hereinafter referred to as "the Territory", under the conditions set forth in the present Contract provided THE LABORATORY undertakes to order all its supplies in Product for the Territory exclusively from ETHYPHARM and comply with the terms of the present Contract.

Therefore, it has been agreed as follows :

#### Article I - Supply.

*independante de la demande de fabrication*

During the period of this Contract ETHYPHARM will supply for the Territory, such quantities of the Product as will be required by THE LABORATORY. *en fonction de la demande*

#### Article II - Exclusivity.

The counterpart of the engagement of guaranteed supplies by ETHYPHARM to THE LABORATORY under article I above is that THE LABORATORY will take all its supplies exclusively from ETHYPHARM or from another supplier designated by ETHYPHARM for all its needs of the Product in the Territory in order to guarantee the quality of the Product. Moreover, ~~THE LABORATORY may not directly or indirectly manufacture microgranules constituting the Product.~~ *sa la commande de ethypharm*

#### Article III - Orders.

III.1. THE LABORATORY will place its orders at least four (4) months in advance according to its predicted annual requirement, revised every six (6) months.

The said predicted annual requirement will be communicated by THE LABORATORY for information purposes, sixty (60) days before the start of each calendar year and will not constitute a firm commitment by THE LABORATORY.

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Fax émis par : 33141121797

ETHYPHARM ST CLOUD

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Each order placed by **THE LABORATORY** will bear the exact quantity ordered, the delivery date and the address at which the Product must be sent.

The orders will be considered as firm and irrevocable and will bind **ETHYPHARM** as soon as accepted in writing.

**ETHYPHARM** shall accept and deliver all the orders according to the program established by **THE LABORATORY** unless the quantities ordered are substantially different from the quantities indicated in **THE LABORATORY**'s forecasts for the year of the Contract and provided that **ETHYPHARM** receives the order a minimum of four (4) months before the delivery date.

**THE LABORATORY** shall at all times keep adequate stock of the Product to meet the market demand in the Territory. These adequate stocks shall be sufficient for covering the estimated requirement for at least four (4) months.

III.2. In the event of being unable to fulfil its obligations as supplier, for whatever reason, **ETHYPHARM** undertakes to inform **THE LABORATORY** with the minimum delay possible and to find another supplier within a maximum of sixty (60) days. The latter will deliver the order within thirty (30) days on the same terms and conditions.

III.3. Technical and pharmaceutical responsibility and obligations of the parties will be fully detailed in an "Agreement on Contract Manufacturing of Drugs" to be established between the technicians of the parties.

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The supply price of the Product invoiced by **ETHYPHARM** to **THE LABORATORY** will be determined by mutual agreement between the parties according to the conditions set out in Annex B hereto.

#### Article V - Liability

**ETHYPHARM** shall accept responsibility for any claims covered by and limited to the guarantees specified in the insurance policy annexed hereto arising out of latent or hidden defects in the Product which could not have been reasonably discovered by **THE LABORATORY**'s inspection but will not be held responsible for any side effect currently unknown inherent to the characteristics of the Product which is manufactured strictly in accordance with the provisions defined by the registration files accepted by the local Regulatory Authorities.



**Article VI - Indemnity.**

THE LABORATORY shall be exclusively liable for any damages, claims or losses from which THE LABORATORY may suffer by reason of improper packaging, storage, re-packaging, distribution, promotion, marketing and advertising of the Product in the Territory.

ETHYPHARM will, however, be responsible as to the good manufacturing practice and good storage facilities in its plant and warehouses until the goods are collected by THE LABORATORY.

**Article VII - Product recall and adverse reactions.**

Each party shall use reasonable endeavours to obtain and record written medical confirmation and relevant details of all suspected or alleged reactions to the Product (hereinafter called "Adverse Reactions") and shall ensure by means of a written log that all such cases and the dossier relative to it is uniquely identified and retrievable.

**Article VIII - Quality.**

VIII.1. ETHYPHARM shall be responsible for ensuring that, when released by ETHYPHARM, the Product accord to the specifications set out in Annex A hereto.

If the Product is found not to comply with the specifications by local testing authorities within one (1) month from receipt by THE LABORATORY of the Product,

THE LABORATORY shall have the right to demand a refund or replacement thereof and to return the defective quantity to ETHYPHARM at ETHYPHARM's expense. In case of disagreement between the parties as to the compliance of the Product with the specifications, the parties agree to have the Product controlled by an independent expert chosen by the parties and acceptable to the local testing authorities.

The results of such retesting will be binding and the party found in default will bear the costs of retesting and replacement of the Product.

VIII.2. THE LABORATORY and the competent Authorities of the Territory will have the right to inspect ETHYPHARM's production of the Product, at any time, following reasonable notice and during office hours.

**Article IX - Insurance.**

ETHYPHARM and THE LABORATORY warrant that they hold adequate products liability insurance in respect of any claims which may be brought against ETHYPHARM or THE

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N° TX/RX7597

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CONFIDENTIAL

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Fax émis par : 33141121797

ETHYPHARM ST CLOUD A4-A4 03/04/98 17:00 Pg: 7/10

4 ans y compris les

**LABORATORY** in relation to the Product and will supply each other with a copy of the relevant policy on request.

#### Article X - Duration.

This Contract shall be effective immediately upon its signature and shall remain in effect for a period of ten (10) years from the date of first launch of the Product in the Territory.

At the end of this initial period of ten (10) years, this Contract will be automatically renewed per periods of three (3) years unless terminated by any of the parties twelve (12) months prior to the end of the initial period or any of the renewal period by registered mail.

#### Article XI - Termination.

Each party reserves the right to cancel this Contract at any time and without indemnification if the other party commits a material breach of its obligations and fails to remedy this breach within ninety (90) days of the notification of said breach by registered letter.

#### Article XII - Confidentiality.

All the information relative to the Product or to the know-how communicated by **ETHYPHARM** to **THE LABORATORY**, will be considered by **THE LABORATORY** as strictly confidential and will not be divulged by **THE LABORATORY** to third parties without prior agreement in writing by **ETHYPHARM**. The subsidiaries, licensees, or overseas agents of **THE LABORATORY** outside the Territory are considered as third parties.

This obligation shall continue for five (5) years beyond the expiry of this Contract for any reason. Nevertheless, it will not apply to information which must be given to physicians for sales purposes or to the authorities for the purpose of registering the Product in the Territory.

#### Article XIII - Contractual relationship.

**XIII.** This Supply Contract constitutes the whole agreement between the parties and replaces any former agreement relative to the same subject. Modifications to this Contract will be made in writing only, and will have to be accepted and signed by both parties.

**XIII.** If one of the provisions of the present Supply Contract interferes with local legislation in force in the Territory, then this particular provision will be modified by the parties in order to comply with local legislation. This modification will not affect the other provisions of this Contract.

03/04 '98 17:03

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ETHYPHARM ST CLOUD

A4-A4 03/04/98

17:00

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#### Article XIV - Jurisdiction.

In the event of difficulties between the parties as to the interpretation of this Agreement, the parties agree to submit these difficulties to the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the Rules and decisions of the ICC. The arbitrator (s)' decisions shall be binding on both parties hereto.

The applicable law will be Spanish law and arbitration place will be Madrid (Spain). The arbitration proceedings will be conducted in English language.

#### Article XV - Transfer.

THE LABORATORY may not transfer its rights or obligations arising from this Contract without the prior written consent of ETHYPHARM.

#### Article XVI - Costs and fees.

The costs and fees of any possible registration or legalisation of this Contract are to be borne by THE LABORATORY.

Signed in  
For :

Date :  
For : ETHYPHARM S.A. Spain  
Patrice DEBREGEAS  
President

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03/04 '98 17:03

N° TX/RX7597

P.008

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ETHYPHARM ST CLOUD

A4->A4 03/04/98 17:00 Pg: 9/10

**Annex A to the Supply Contract Between**

..... and ETHYPHARM S.A. Spain

OMEPRazole 20 mg per dose in the form of microgranules according to the specification established by the analytical dossier. *a line for indication*

a la for. vol. 100  
Quinta.

Formulário

- 7 -

03/04 '98 17:03

Nº TX/RX7597

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ETHYPHARM ST CLOUD

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17:00

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**Annex B to the Supply Contract between**

....., and ETHYPHARM S.A. Spain

The supply exclusivity defined in Article II means that **THE LABORATORY** will take exclusively from **ETHYPHARM** all its requirements of the Product.

1.1. The supply price of the Product, delivered in ....., is expressed ..... and fixed at :

- 20 mg : ..... per thousand doses taxes excluded.

This price includes .....

Moreover, it is valid for minimum batches of doses corresponding to .....

1.2. Should **THE LABORATORY** wish to order a smaller quantity than the standard batch above mentioned **ETHYPHARM** may apply a supplement of 30 % of the price if the quantity lies between 50 % and 100 % of a normal batch and a supplement of 50 % of the price if the quantity ordered is less than 50 % of the normal batch.

2. All payments will be made by ..... within ..... from date of shipment of goods from **ETHYPHARM** (date of AWB for example).

3. The price set out in this Annex is guaranteed until ..... and will vary each year in accordance with the salary increase of the "Convenio de la Industria Quimica" in Spain.

*de unido*

*ordinous*

*minimales*

*ordinous de pago*

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<http://www.ethypharm.com>

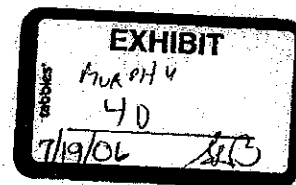
- Tel +33 1 4112 1720
- Fax +33 1 4112 1730
- E Mail [contact@ethypharm.com](mailto:contact@ethypharm.com)
- Visioconf +33 1 4112 0075

194, Bureaux de la Colline -  
92213 SAINT CLOUD CEDEX- FRANCE

To	Mr James MURPHY	From	Mr Gérard LEDUC
Cie	BENTLEY	Cc	Roseline JOANNESSE
Cc		Fax	+ 33 1 4112 1745
Fax	00 1 603 964 6889	Tel	+ 33 1 4112 1720
Tel	00 1 603 964 8006	e-Mail	Leduc.gérard@ethypharm.com
	32 (cover page included)		June 8, 2001
Page(s)		Date	

Attached :

- \* Letter from Gérard LEDUC
- \* Draft of Agreement - Belmac



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\* Draft of Agreement - Belmac

\* Letter from Gérard LEDUC

Attached :